DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
Rockville MD 20857

#24

Re: MYCOBUTIN™
Docket No. 93E-0099

JUN -8 1994

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DEPUTY ASSISTANT
COMMISSIONER FOR PATENTS

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the application for patent term extension for U.S. Patent No. 4,219,478, filed by Adria Laboratories, under 35 U.S.C. § 156 et seq. The Food and Drug Administration (FDA) is correcting the notice of its determination of the regulatory review period for purposes of patent extension for MYCOBUTIN™ (rifabutin) that appeared in the Federal Register of April 15, 1994 (page 18,133). The notice stated:

> FDA has determined that the applicable regulatory review period for MYCOBUTIN™ is 2,831 days. Of this time, 2,124 days occurred during the testing phase of the regulatory review period, while 707 days occurred during the approval phase.

It should have stated:

> FDA has determined that the applicable regulatory review period for MYCOBUTIN™ is 2,469 days. Of this time, 2,127 days occurred during the testing phase of the regulatory review period, while 342 days occurred during the approval phase.

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: Mark P. Levy, Esq.
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